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(21) International Application Number: PCT/US96/18108 (22) International Filing Date: 12 November 1996 (12.11.96) (30) Priority Data: 08/554,993 13 November 1995 (13.11.95) US (71) Applicant (for all designated States except US): BIO MED SCI- ENCES, INC. [US/US]; 101 Technology Drive, Bethlehem, PA 18015 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): DILLON, Mark, E. [US/US]; 2830 Linden Street #5C, Bethlehem, PA 18017 (US). (74) Agents: EARLEY, John, F., A. et al.; 86 The Commons at Valley Forge East, 1288 Valley Forge Road, P.O. Box 750, Valley Forge, PA 19482-0750 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>
(54) Title: THERAPEUTIC MEDICAL GARMENTS FOR SCARS AND PROCESS (57) Abstract Therapeutic medical garments for scar treatment includes a composite fabric for treating dermatological scars, wherein a layer of textile fabric and a layer of a therapeutic agent produce a composite sheet suitable for the treatment of dermatologic scars resulting from traumatic, surgical or other injuries to the skin. The composite sheet may be fashioned into garments fitted to the patient for convenience of use, optimization of skin contact, and single step application of pressure therapy and the therapeutic agent. A process of use of the medical garment for applying therapeutic agent and pressure therapies.		

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THERAPEUTIC MEDICAL GARMENTS FOR SCARS AND PROCESS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to therapeutic medical garments for the treatment of scars, and more specifically for the prevention or management of hypertrophic scars and keloids.

2. Description of the Prior Art

5 Therapeutic medical binder garments have been used for many years to apply pressure to anatomic regions after surgical procedures such as reduction mammoplasties, abdominoplasties, and rhytidectomies (face-lifts). Similar pressure application garments have become a standard of care
10 in the management of hypertrophic scars and keloids subsequent to burn injuries.

As disclosed in my co-pending patent application serial no. 08/200,152 filed February 23, 1994, silicone elastomer materials are also used in the medical field for the
15 management of dermal scarring which often results from

burns, traumatic injuries, or surgical incisions. These silicone materials soften scar tissue and improve the cosmetic as well as functional aspects of such scars over a period of weeks and months. The biological mechanism for this effect is poorly understood. It is, however, known that the therapeutic benefit is derived independently of pressure applied to the scar surface.

It is common practice in the scar management field to combine pressure therapy with silicone sheeting in highly critical areas such as the hands or face, or other areas of aesthetic importance. In this fashion, a maximum effect can be achieved in a minimum amount of time.

Difficulties arise in placing silicone sheeting materials under textile garments over complex contours of the body. These difficulties primarily relate to an inability to avoid wrinkles and folds in the silicone elastomer, patient compliance with the tedious application on a daily basis, positioning and maintenance of the sheet during movement, and providing optimal skin contact.

My co-pending patent application no. 08/200,152 discloses an interpenetrating polymer network (IPN) of silicone and polytetrafluoroethylene (PTFE) which has improved physical properties while having decreased thickness. While it is possible to apply the IPN material over complex anatomical contours under pressure application devices without folds or gaps, it is still a tedious task and maintaining position remains difficult.

For the purpose of this invention, the terms silicone

elastomer, silicone gel, or silicone IPN will be equivalent and used interchangeably, since it is believed that this invention may be accomplished with any of these materials.

SUMMARY OF THE INVENTION

5 This invention relates to scar treatment and more particularly to a composite structure for scar treatment which incorporates the convenience and simplicity of donning garments. Further, this invention relates to composite structures which incorporate the pressure therapy features
10 of therapeutic medical binder garments with the use of silicone elastomers for scar management.

 By applying a surface layer of silicone elastomeric material to one side of a suitable textile fabric prior to garment fabrication, I have unexpectedly discovered that
15 shaped garments may be produced which provide a surface layer of silicone for uniform skin contact even when shaped into complex geometric forms. The finished product is easily donned and maintains the position of the silicone sheeting material with respect to the application site. In
20 addition, the material is durable and capable of being machine washed and dried.

 The therapeutic medical garments of this invention are made of a soft silicone elastomer layer bonded to a textile fabric layer, and the silicone elastomer layer is placed in
25 contact with the patient's skin.

 The manufacturing process lends itself to large-scale production in that flat sheets are produced for final shape-

forming by traditional garment manufacturing processes. This provides for rapid and cost effective production of ready-to-wear or custom made shapes for any given patient.

This invention is an improvement over the prior art in that (a) the silicone layer is bonded to the surface of an elastic textile fabric to produce a therapeutic medical garment, (b) the medical garment is easily donned without creating folds or gaps between the silicone layer and the skin, (c) both pressure and silicone therapies may be applied concomitantly without requiring a separate and/or repeated process of fitting both materials to the skin individually, and (d) patient compliance may be improved because daily application of the therapy is greatly facilitated.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of one embodiment of this invention wherein a silicone elastomer layer 10 is bonded to an elastic textile fabric layer 20 to form a composite fabric 30.

Figure 2 is a plan view of a therapeutic medical garment with regions (A) and (B) constructed of the composite layer formed by the silicone and textile layers of this invention.

DETAILED DESCRIPTION OF SEVERAL EMBODIMENTS

A preferred embodiment of this invention is shown in the following illustrative examples and is not intended to

be limiting.

There are many silicone compositions that are suitable for use in this invention, either in combination or in blends. In addition, current clinical investigations indicate that other materials, such as hydrogels or hydrocolloids, may be similarly effective for scar reduction and therefore also useful for this invention. However, hydrogels and hydrocolloids in general, as well as many silicone containing compounds, such as silicone copolymers containing mineral oil, lack sufficient durability to provide reasonably economical use in the garment which must last for months.

There are numerous textile fabric materials which may be useful for the purpose of this invention. Furthermore, various thicknesses of textile fabric layers and layers of therapeutic agent may be useful, and components of various elasticities could be used. The primary consideration is that the medical garment of this invention has suitable tactile qualities that make it comfortable for the patient to wear, applies pressure that is suitable, and has an efficacious therapeutic agent which is applied to the skin where needed. It is also important that the finished product is capable of being washed by ordinary methods, and that the product has sufficient durability to allow repeated use and cost effectiveness.

Example 1

My U.S. Patent Application No. 08/200,152, discloses a

method of manufacturing a simultaneous interpenetrating polymer network (IPN) of silicone and polytetrafluoroethylene (PTFE). The process involves using a release liner as a carrier substrate onto which the elastomer sheeting is formed. The substrate is passed through a coating station which deposits a layer of the uncured silicone/PTFE mixture. The carrier is then passed through a tunnel style oven to vulcanize the silicone.

The silicone layer was tightly bound to the textile fabric and could not be removed from its surface using mechanical techniques. Samples of fabric were washed and dried using an ordinary household washing machine and drier (five) times according to Military Specification-44187B test method 4.5.5. without signs of delamination or wear.

A commercially available brassiere from Playtex Apparel, Inc. was purchased from a retail outlet. The cup panels of the garment were removed and replaced with the silicone textile composite material of this invention such that the silicone surface of the composite textile material faced inward to provide contact with the patient's skin. The resulting product was a single piece garment suitable for scar reduction therapy of, for example, reduction mammoplasty incisions.

In this example, a commercially available brassiere was remodeled to use the composite layers of this invention. It is obvious that a garment may be initially manufactured with fabric panels comprised of the composite layers of this

invention. An ordinary cutting pattern may be utilized, with the silicone textile composite layer used for the appropriate panel cuts and ordinary fabric used for the remainder. In addition, a variety of brassiere designs
5 would be suitable for similar use.

Numerous other types of therapeutic medical garments may be produced by the process disclosed above. Other similar articles include abdominoplasty garments, facial slings for rhytidectomy procedures, and the like. In
10 addition, various forms of therapeutic medical binders used for burn scar management may likewise be produced, such as gloves, facemasks, vests, etc. Garments of a less compressive design are also useful to promote comfort and use beyond the period where the function of a binder garment
15 is desired. Furthermore, it is contemplated that the finished product may be supplied in sheets for custom tailoring by a clinician.

Claims:

1. A composite article, suitable for the treatment of dermatologic scars, comprising

a first layer of a therapeutic agent, and

a second layer of a textile fabric capable of being
5 formed into garments.

2. A composite article of claim 1, wherein the therapeutic agent is a compound containing silicone.

3. The composite article of claim 1, wherein the therapeutic agent is an interpenetrating polymer network of silicone and polytetrafluoroethylene.

4. The composite article of claim 1, wherein the fabric of the second layer is a textile comprised of a blend of 89% nylon and 11% Spandex.

5. A composite article, suitable for the treatment of dermatologic scars, comprising

a first layer of a therapeutic agent, and

a second layer of a textile fabric capable of being
5 formed into garments, wherein

the therapeutic agent is a silicone containing compound, and

the fabric of the second layer is a textile comprised of a blend of 89% nylon and 11% Spandex.

6. A composite article, suitable for the treatment of dermatologic scars, comprising

a first layer of a therapeutic agent, and

a second layer of a textile fabric capable of being
5 formed into garments, wherein

the therapeutic agent is an interpenetrating polymer network of a silicone and polytetrafluoroethylene, and

the fabric of the second layer is a textile comprised of a blend of 89% nylon and 11% Spandex.

7. A garment for treating dermatologic scars, suitable for donning, and capable of being machine washed and dried, at least one section of which comprises:

a composite textile containing a skin contacting
5 surface comprised of a therapeutic agent suitable for the treatment of dermatologic scars.

8. The article of claim 7, wherein the therapeutic agent of the composite textile is a silicone containing compound.

9. The article of claim 7, wherein the therapeutic agent of the composite textile is an interpenetrating polymer network of silicone and polytetrafluoroethylene.

10. The article of claim 7, wherein the textile fabric is a blend of 89% nylon and 11% Spandex.

11. The article of claim 7, wherein
the therapeutic agent of the composite textile is an
interpenetrating polymer network of silicone and
polytetrafluoroethylene, and
5 the textile fabric is a blend of 89% nylon and 11%
Spandex.

12. The article of claim 7, wherein the garment is
fashioned as a brassiere.

13. A process of producing a composite article
suitable for the treatment of dermatologic scars, comprising
passing a sheet of textile fabric through a coating
apparatus, and
5 depositing a surface layer of a therapeutic agent onto
said textile fabric, and
fabricating a garment from said coated textile fabric.

14. The process of claim 13, wherein
the textile fabric is comprised of a blend of 89% nylon
and 11% Spandex.

15. The process of claim 13, wherein
the therapeutic agent is a silicone containing
compound.

16. The process of claim 13, wherein
the therapeutic agent is an interpenetrating polymer

network of silicone and polytetrafluoroethylene.

17. The process of claim 13, wherein
the textile fabric is comprised of a blend of 89% nylon
and 11% Spandex, and

the therapeutic agent is an interpenetrating polymer
5 network of silicone and polytetrafluoroethylene.

18. A process of using a therapeutic medical garment
for scar treatment, comprising the steps of:

passing a sheet of textile fabric through a coating
apparatus,

5 said fabric having a controlled elastic stretch,
depositing a sheet of a therapeutic agent onto the
textile fabric to form a composite sheet of a therapeutic
layer and a stretchable layer,

fabricating a therapeutic medical garment from the
10 composite sheet that is fitted to the patient and is
comfortable to wear,

placing the therapeutic medical garment on the patient
with the therapeutic layer facing the patient,

contacting the skin of the patient with the therapeutic
15 agent from the therapeutic layer,

and elastically holding the therapeutic layer onto the
skin of the patient by the elastically stretchable layer to
exert pressure therapy on the patient as well as the
therapeutic agent therapy.

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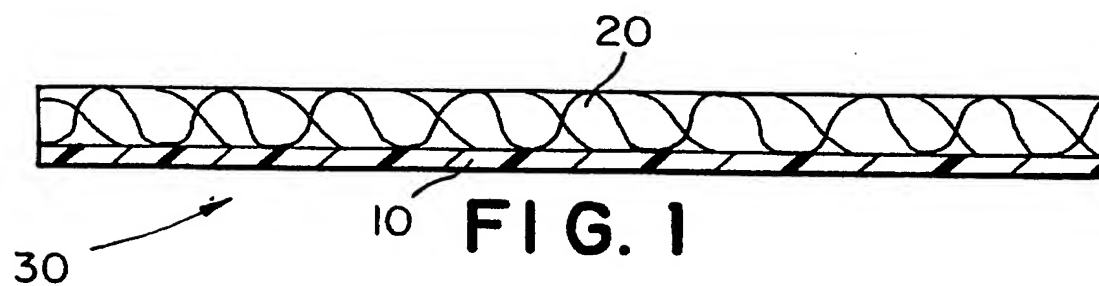


FIG. 2

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/18108**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61F 13/00; A61L 15/16

US CL :424/422, 443, 444

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/422, 443, 444

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,832,009 A (DILLON) 23 May 1989, column 1, lines 9-14 and 44-47 and column 2, lines 34-38.	1-18



Further documents are listed in the continuation of Box C.



See patent family annex.

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